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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,093	07/31/2002	Peter York	0113.00	7330
21968	7590	11/02/2006	EXAMINER	
NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			SILVERMAN, ERIC E	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,093

Applicant(s)

YORK ET AL.

Examiner

Eric E. Silverman, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-68, 70-75 and 83-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-68, 70-75 and 83-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/22/2006 has been entered.

Claims 60 – 68, 70 – 75, 83 – 86 are pending in this action.

Response to Amendment

The declaration under 37 CFR 1.132 filed 9/22/2006 is sufficient to overcome the rejection of claims 60 – 68, and 70 – 75 based upon 35 USC 102 and 35 USC 103 under Hanna 1 or Hanna 1 in view of Hanna 2.

Double Patenting

The provisional obviousness-type double patenting rejection of claim 54 as being unpatentable over claim 29 of copending Application No. 10/514,895 is **maintained**.

Applicant did not argue that this rejection is improper. As such, it must be maintained.

Claims 60 – 68, 70 – 75, 83 – 86 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, of **Allowed** U.S. Patent Application 11006464. Although the conflicting claims are not identical, they are not patentably distinct from each other because while copending

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claims do not recite the degree of crystallinity which results from the performance of the method, it is understood that the same method will produce the same results, and as such, copending method will produce the same degrees of crystallinity as recited in instant claims.

This rejection is provisional since the copending claims have not actually issued as a patent. However, since the copending claims are allowed this rejection must be addressed before instant claims can be in condition for allowance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60 – 68, 70 – 75, 83 – 86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a written description rejection.**

The Application lacks written description for the following broad genres, which are claimed in the independent claims:

- 1) the genus of “near-critical or supercritical fluid”
- 2) the genus of “active substances”
- 3) the genus of “oligomeric or polymeric materials”

With regard to the genus of "near-critical or supercritical fluids", the only such fluid disclosed to be useful in the invention is supercritical carbon dioxide. Thus, it is not clear that Applicants' actually possessed methods involving any other such fluids. To the extent that one species can sometimes provide written description for an entire genus, it is noted that in this case, there is no teaching of the properties of supercritical carbon dioxide that make it useful in the invention. Thus, it is not recognized from the teachings of the originally filed disclosure that methods were possessed with any other material that might serve in the place of supercritical carbon dioxide. As such, a person of ordinary skill in the art would not recognize that Applicant had possession of the entire claimed genus.

With regard to the genus of "active substances", it is noted that all of the active substances which are shown to be useful in the invention are organic molecules of low molecular weight. This is not sufficient to provide written description for all active substances, the genus of which includes many materials which are not organic molecules of low molecular weight. As examples of types of active substances which are not described, there are inorganic salts such as sodium chloride, iron oxide, also, proteins, polymeric active substances, DNA, RNA, and so on. Clearly, the showing of several low molecular weight organic materials does not sufficiently describe a method utilizing the genus of all "active substances".

With regard to the genus of "oligomeric or polymeric materials", only a few of such materials are disclosed as being useful in the invention. This is not sufficient to show possession of a method including all "oligomeric or polymeric materials",

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especially since there is no teaching as to the properties or structure of the oligomeric or polymeric materials that makes them useful in the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 63, 34, 68, 72, and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "derivatives thereof". Absent a limiting definition in the specification, the artisan would not be certain as to what is encompassed by this phrase. Specifically, the artisan would not know if a particular substance is a "derivative" of the claimed materials.

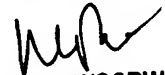
Conclusion

No claims are allowed. The claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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SUPERVISORY PATENT EXAMINER
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